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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,575	11/14/2003	Stelios Tzannis	0180.00	1780

21968 7590 02/13/2007

NEKTAR THERAPEUTICS
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EXAMINER	
KIM, YUNSOO	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
02/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/714,575	Applicant(s) TZANNIS ET AL.	
	Examiner Yunsoo Kim	Art Unit 1644	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 17 January 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: 31-59.
   Claim(s) withdrawn from consideration: 1-30 and 60-74.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

Continuation of 11. does NOT place the application in condition for allowance because:

1. Claims 31-59 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

Applicants' arguments filed 1/17/07 have been fully considered but they were not persuasive.

Applicants argue that the claimed invention is enabled and the support for the phrase "within about 10 minutes" provide the support for "within 10minutes".

The specification as file does not provide a written description for the phrase "visually clear reconstituted composition within 10 minutes of being formed". The specification on p. 23 lines 1-2 discloses the general reconstituting time "within about 10 minutes" and the limitation is not associated with the claimed antibody concentration ranges, especially at about 1000mg/ml. As is evidenced by the specification of instant application on p. 41 (Table VII), the claimed diluent exceeds reconstituting time of 10 min at 190 mg/ml concentration. In addition, the term" about" extends the range of time to recite more than 10minutes.

2. Claims 31-59 stand rejected under 35 U.S.C. 102 (b) as being anticipated by U.S.Pat. No. 6,267,958 (IDS reference AK, of record) for the reasons set forth in the office action mailed 9/25/06.

Applicants' arguments filed 1/17/07 have been fully considered but they are not persuasive.

Applicants traversed the rejection based on that the newly recited limitation upon entry of the amendment was not taught in the '958 patent and the spray dried formulation reconstituted much faster than the corresponding lyophilized starting material.

As indicated in the office action mailed 9/25/06, the claimed invention is drawn to a reconstituted antibody formulation comprising an antibody formed from a spray-dried powder and an excipient. The patentability of the product does not depend on its method of production. The claimed antibody formulation and the referenced antibody formulation both comprise an antibody, diluent, buffer and sucrose as an excipient (claims 1-8, 47 col. 17, lines 1-40, in particular). Thus, the newly claimed product feature being visually clear upon reconstitution is inherent property of the antibody formulations.

Applicants argue that the spray dried formulation reconstituted much faster than the corresponding lyophilized starting material shown in [0162]. However, the sample test as in [0162] was performed in the distilled water and cannot be extrapolated into the claimed diluent. In addition, the referenced antibody concentration is at 50mg/ml and cannot be extrapolated into the claimed concentration range of about 1000mg/ml. The specification of instant application on p. 41 (Table VII) discloses that the claimed diluent exceeds reconstituting time of 10 min at 190 mg/ml concentration and it is less likely to reconstitute 1000mg/ml antibody within 10min. Thus, prior art teachings anticipate the claimed invention.

Yunsoo Kim
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Technology Center 1600
February 7, 2007

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